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JUL 1 0 2000

Medibell
Medical Vision Technologies Ltd.

510(K) Summary of safety and Effectiveness

Submitter :	**Medibell- Medical Vision Technologies Ltd. MATAM, Haifa 31905 Israel**
Establishment Reg.:	_____
Contact:	**Ilan Sharon Consultant**
Summary Date:	_____

Name of Device and Classification

Proprietary Name:	**PANORET 1000A**
Common Name:	**High Resolution Digital Imaging System**
Classification:	**Accessory to 21 CFR 886.1120, Class II**

Predicate Device

Manufacturer:	**Chromos Imaging, Imaging.**
Predicate Name:	**Chromos Imager**
510(K) Number:	**K923958**

Medibell - MATAM, Haifa 31905, Israel,
Tel: 972-4-8500058 or 972-4-8566220 (ext. 257), Fax: 972-4-8550249
מרכז תעשיות מדע, חיפה 31905, טל': 04-8500058/04-8566220(257) , פקס': 04-8550249

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Intended Use

The PANORET 1000A allows the acquisition of clinical digital images of the interior of the eye (the retina), the anterior segment (cornea, iris, lens) and the external eye due to the ophthalmic optical design. Acquisition and display are enabled in high-resolution (1024x1024) for color or monochrome mode of operation.

Fields of application of the system are: color examination and recording data of the different parts of the eye, monochromatic imaging using restricted light to isolate pathological findings, fluorescein angiography studies and clinical images of the external eye.

Comparison to the Predicate

Both systems have the same intended use. Both systems are computer controlled devices, although different platforms and different operating system but in the mainstream of today's computer technologies.
The relevant differences that added to the *Panoret 1000A* came to improve the ophthalmic examination performances and the quality resolution of acquired images. The main differences are: field of view, the CCD camera, the illumination delivery concept and the supporting arm.

NOTE: The *Chromos Imager* is not marketed anymore at the moment and the system named *RetCam* from Massie Research Laboratories, Inc. is marketed instead the predicated device. The *RetCam* is based on the *Chromos Imager* technologies and the respective features. See section J (Additional Relevant Literature).

Safety Information

The *Panoret 1000A* is designed to comply with the minimum response requirements stated in the initial Hazard Analysis included in the notification, and with voluntary international standard IEC 60601-1 for medical electrical equipment regarding both its safety (part 1) and electromagnetic compatibility (part 2) requirements.

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After completion of the pre-production series, the device will be submitted for compliance tests with the above mentioned requirements in a certified laboratory.

Prior to commercial distribution, the system will be β tested to meet specifications including safety requirements.

Conclusions

We conclude that, once finished the development and testing phase as described, the *Panoret 1000A* will be safe and effective as the predicate device.

Mario Kuszpet Ph.D.
Managing Director

APRIL 3, 2000
Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Mario Kuszpet
Managing Director
Medibell Medical Vision Technologies Ltd.
Matam
Haifa 31905, Israel

Re: K001111
Trade Name: Panoret, Model 1000A
Regulatory Class: II
Product Code: 86 HKL
Dated: June 20, 2000
Received: June 22, 2000

Dear Dr. Kuszpet:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Device Name: ***PANORET 1000A***

Indications for Use:

The PANORET 1000A is a diagnostic device intended to provide digital photographs of the interior of the eye as well as the anterior segment and external part of eye.

(PLEASE, DO NOT WRITE BELLOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001111

(Optional Format 3-10-98)